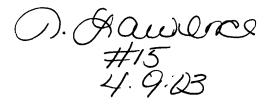


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PATENT 130-125

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re US Patent Application of)
Thomas W. Astle)
Serial No. 09/198,018)
Filed: November 23, 1998)
Title: ULTRA HIGH THROUGHPUT)
BIOASSAY SCREENING SYSTEM)

Assistant Commissioner for Patents Washington DC 20231

BRIEF OF APPELLANT

This is an appeal from the final rejection of the Examiner, dated October 25, 2002 (Paper No. 14), rejecting Claims 1-18, 21-23, and 30.

REAL PARTY IN INTEREST [37 CFR 1.192(c)(1)]

The real party in interest is the party named in the caption.

RELATED APPEALS AND INTERFERENCES [37 CFR 1.192(c)(2)]

There are no related appeals or interferences.

STATUS OF CLAIMS [37 CFR 1.92(c)(3)]

The status of the claims set out in Paper No. 14 was and is:

Claims pending: 1-30.

Claims withdrawn from consideration: 19, 20, and 24-29.

Claims allowed: none.

Claims objected to: none.

Claims rejected: 1-18, 21, 23, and 30.

SUMMARY OF THE INVENTION [37 CFR 1.192(c)(5)]

Applicant's invention is directed to a carrier tape and its use in ultra high throughput bioassay screening of as many as 100,000 samples per day.

Referring first to Figure 1, there is illustrated a portion of a carrier tape 20 having a plurality of repetitive patterns of wells, as at 30, with a plurality of holes, as at 70, defined between the wells, for the application of vacuum, as is described below with reference to Figure 4. Sprocket holes, as at 32, are provided so that the carrier tape may be moved by a sprocket drive, as is illustrated on Figure 11. Figure 2 illustrates the size of the wells.

Referring to Figure 5, there is illustrated the application of a heat seal layer 62 to the tops of wells 30. Thereafter, a vacuum applied through holes 70, as illustrated on Figure 4 removes any air trapped between the carrier tape and the heat seal layer to assure tight sealing of the wells. Carrier tape 20 then passes through a series of heat controlled baths, as is illustrated on Figure 8 after which heat seal layer 62 may be removed.

Importantly, 100,000 chemical compounds, in 5 microliter aliquots, can be stored in a carrier tape roll 4 inches wide by 16 inches in diameter. See the Specification, page 11, lines 7-10.

ISSUES [37 CFR 1.192(c)(6)]

- The Examiner has rejected claims 9-13 under 35 USC 112, first paragraph as containing subject matter not in the disclosure. It is the Examiner's position that the instant disclosure does not exclude the use of a knife structure.
- 2. The Examiner has rejected Claims 9-13 under 35 USC 112, second paragraph as being indefinite. It is the Examiner's position that Claim 9 contains the phrase "knife structure" not used in the disclosure and that Claim

15 (which is not under Claims 9-13) contains the word "near" which is considered to be undefined.

- 3. The Examiner has rejected Claims 1, 2, 21, 22, and 30 under 35 USC 102(b) as being anticipated by Guigan. It is the Examiner's position that Guigan shows all the limitations of the claims.
- 4. The Examiner has rejected Claims 21 and 22 under 35 USC 102(b) as being anticipated by Howell. It is the Examiner's position that Howell shows Applicant's carrier tape and a sealing material placed thereover.
- 5. The Examiner has rejected Claims 3-8, 16-18, and 23 under 35 USC 103(a) as being unpatentable over Guigan in view of Anderson. It is the Examiner's position that it would have been obvious to employ the unique identifier of Anderson in the device of Guigan, that Anderson teaches diecutting the sealing material around the wells, and that Anderson teaches cutting out segments along perforations of the carrier tape with samples. Furthermore, the Examiner states that it would have been obvious to use Applicant's claimed material and size.
- 6. The Examiner has rejected Claim 23 under 35 USC 103 as being unpatentable over Howell. It is the Examiner's position that it would have been obvious to form a roll having the claimed dimensions.
- 7. The Examiner has rejected Claims 9-13 under 35 USC 103(a) as being unpatentable over Guigan in view of Hansen et al. It is the Examiner's position that it would have been obvious to use the pressure sensitive adhered sealing material of Hansen et al. in the Guigan device, as claimed by Applicant.
- 8. The Examiner has rejected Claims 9-13 and 15 under 35 USC 103(a) as being unpatentable over Guigan in view of Tidemann et al. It is the

Examiner's position that it would have been obvious to use the pressure sensitive adhered cover of Tidemann et al. in the device of Guigan and, in view of Tidemann et al., to evacuate the space between the cover and the wells.

9. The Examiner has rejected Claim 14 as being unpatentable over Paquette. It is the Examiner's position that the heated knife of Paquette renders obvious Applicant's use of a heated roll.

GROUPING OF CLAIMS [37 CFR 1.192(c)(7)]

To the extent that arguments are presented below with respect to specific claims, it is Applicant's intention that those claims shall not stand or fall together with the claims with which they are grouped.

ARGUMENT [37 CFR 1.192(c)(8)]

<u>Issue 1</u> – the rejection of Claims 9-13 under 35 USC 112, first paragraph.

Applicant's disclosure only describes pulling the seal from the carrier tape and, specifically, the use of a heated roll to facilitate that operation. See Figure 5 and the accompanying text. It is respectfully submitted that the absence of a knife structure is inherent in the disclosure.

<u>Issue 2</u> – the rejection of Claims 9-13 under 35 USC 112, second paragraph as being indefinite.

The Examiner asserts that "without the use of a knife structure" renders Claims 10 and 11 indefinite. That question has been addressed above.

In the apparent rejection of Claim 15 under 35 USC 112, second paragraph, for the use of the word "near", it is respectfully submitted that one skilled in the art would immediately know what was being claimed by inspection of Figures 1 and 4 and the accompanying text.

<u>Issue 3</u> – the rejection of Claims 1, 2, 21, 22, and 30 under 35 USC 102(b) as being anticipated by Guigan.

Guigan discloses <u>sequentially</u> addressing the wells. Applicant's amended Claim 1 states that a plurality of wells is disposed on a matrix and that a chemical compound is <u>simultaneously</u> added to all the wells. "Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claims." Lindemann

Chowy is One working a Sie working a Composite to Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (CAFC 1984). It is respectfully submitted that Guigan fails as a reference.

With regard to Claim 2, Figures 3 and 18 of the reference do not show a liquid-tight seal. In fact, the description of Figure 1 states that openings 4 are left for access to the capsules. It must be assumed that similar openings are provided in other embodiments, since there is nothing stated to the contrary in Guigan. Guigan also does not show placing a liquid-tight seal over all wells in a matrix, as claimed. Also, Guigan does not show matrices at all. All the wells of Guigan are in a single line, not a matrix.

With regard to Claims 21 and 22, the above comments with respect to Claims 1 and 2 are applicable and are incorporated here.

With regard to Claim 30, Guigan does not show two or more matrices.

<u>Issue 4</u> – the rejection of Claims 21 and 22 under 35 USC 102(b) as being anticipated by Howell.

It is not seen that Howell teaches chemical wells disposed in two or more matrices on a carrier tape.

Issue 5 – the rejection of Claims 3-8, 16-18, and 23 under 35 USC 103(a) as being unpatentable over Guigan in view of Anderson. The above remarks with respect to Guigan are incorporated here.

With respect to Claims 3-7 and 23, it is respectfully submitted that the combination of the references does not render obvious the claimed dimensions and materials.

With respect to Claims 8, 16, and 18, it is respectfully submitted that Anderson, like Guigan, does not disclose the use of a matrix. Both references disclose only a single line of samples and the combination cannot render obvious the use of a matrix.

The Examiner cites In re Rose for the proposition that a change of size is generally within the level of ordinary skill in the art. The In re Rose case

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involved a relatively small change in the size of bundled lumber. In the present case, size is one important defining element over the prior art and any modification of the references would involve considerably more than a mere change in size.

The Examiner has made no comment with respect to the limitations of Claim 17 and the combination of the references offers no indication that the contents of chemical receiving wells can be forced to the bottom of the wells by centrifugal force created by spinning.

<u>Issue 6</u> – the rejection of Claim 23 under 35 USC 103(a) as being unpatentable over Howell.

It is not seen that Howell forms any film containing samples into rolls, much less a roll having the dimensions claimed by Applicant.

<u>Issue 7</u> – the rejection of Claims 9-13 under 35 USC 103(a) as being unpatentable over Guigan in view of Hansen et al.

Using the adhered layers of Hansen et al. in the device of Guigan, if such a combination could be made, would seem to destroy the function of the device of Hansen et al. "Where the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, the proposed modification would not have been obvious." See Tec Air Inc. v. Denso Mfg. Michigan Inc. 192 F3d 1353, 1360, 52 USPQ 2d 1298 (CAFC 1999). It is respectfully submitted that the combination of the references falls squarely within this rule.

<u>Issue 8</u> – the rejection of Claims 9-13 and 15 under 35 USC 103(a) as being unpatentable over Guigan in view of Tidemann et al.

It is respectfully submitted that Tidemann et al. do not disclose the use of a seal, but, rather, a discloses a cover that may be temporarily applied to a carrier by the use of hook-and-loop fabric – hardly a seal. Applicant's invention as claimed in Claims 9-10 is directed to the "seal" as shown on Figures 3-5 and

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described in the accompanying text. Combining the two references does not make the cover of Tidemann et al. a seal. Tidemann et al. adhere the cover only to the edges of the carrier.

Claims 11-13 are directed to specific materials not rendered obvious by the combination of the references.

With respect to Claim 15, that claim specifies that the holes are located near upper edges of the chemical receiving wells. The holes of Tidemann et al. are located at the bottom of the wells. Applying vacuum to the holes of Tidemann et al. would suck out the liquid in Applicant's invention or that of the device of Guigan. Consequently, there would be no object in combining the references.

<u>Issue 9</u> - the rejection of Claim 14 under 35 USC 103(a) as being unpatentable over Guigan in view of Paquette.

Paquette uses a heated knife structure to strip a cover from a slide plate filter. Applicant does not employ a heated roll as is particularly pointed out and distinctly claimed in Claim 14. It is not seen that combining Paquette with Guigan renders obvious the use of a heated roll, as claimed by Applicant.

In view of the above, it is respectfully submitted that the Examiner's rejection is in error and should be reversed.

March 27, 2003.

Respectfully submitted,

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APPENDIX [37 CFR 1.192(c)(9)]

The following sets forth all claims on appeal.

- 1. A method of chemical compound storage, comprising:
- (a) providing a longitudinally extending carrier tape having therein two or more matrices of thermoformed chemical receiving wells; and
- (b) simultaneously adding to each of said chemical receiving wells in one of said two or more matrices a chemical compound.
- 2. A method of chemical compound storage, as defined in Claim 1, further comprising: simultaneously placing a liquid tight sealing material around each of said chemical receiving wells in one of said two or more matrices to retain said chemical compounds therein and to minimize evaporation.
- 3. A method of chemical compound storage, as defined in Claim 2, further comprising: forming said carrier tape into a compact roll for storage, said roll having about 100,000 aliquots and dimensions of about 16 inches in diameter by four inches wide.
- 4. A method of chemical compound storage, as defined in Claim 1, further comprising: providing said carrier tape of a thermoformable material having a thickness on the order of from about 15 mils to about 20 mils.
- 5. A method of chemical compound storage, as defined in Claim 1, further comprising: providing said carrier tape formed of polypropylene to provide solvent resistance.

- 6. A method of chemical compound storage, as defined in Claim 1, further comprising: providing said carrier tape formed of clear polycarbonate or polystyrene to facilitate optical reading of contents within said chemical receiving wells.
- 7. A method of chemical compound storage, as defined in Claim 1, further comprising: providing said chemical receiving wells in said two or more matrices selected from the group consisting of 8x12 wells with a spacing of 9mm between centers, 16x24 wells with a spacing of 4.5mm between centers, and 32x48 wells with a spacing of 2.25mm between centers.
- 8. A method of chemical compound storage, as defined in Claim 7, further comprising: providing each of said repetitive matrices with a unique identifier.
- 9. A method of chemical compound storage, as defined in Claim 2, further comprising: providing said sealing material with a pressure sensitive adhesive to adhere said sealing material to said carrier tape to permit removal of said sealing material after adhesion to said carrier tape by pulling said sealing material from said carrier tape without the use of a knife structure.
- 10. A method of chemical compound storage, as defined in Claim 2, further comprising: providing said sealing material removably heat sealed to said carrier tape to permit removal of said sealing material after being sealed to said carrier tape by pulling said sealing material from said carrier tape without the use of a knife structure.

- 11. A method of chemical compound storage, as defined in Claim 10, further comprising providing said seal material as a two layer material having:
- (a) a lower, seal layer of a low melting point material inert to the contents of said chemical receiving wells; and
- (b) an upper high melting point layer having a higher tensile strength than said seal layer and being joined to said seal layer, to assist in removing said sealing material from said carrier tape.
- 12. A method of chemical compound storage, as defined in Claim 11, further comprising: providing said lower seal layer formed of a material selected from the group consisting of modified low density polyethylene and ethyl vinyl acetate.
- 13. A method of chemical compound storage, as defined in Claim 11, further comprising: providing said upper layer formed from polyester.
- 14. A method of chemical compound storage, as defined in Claim2, further comprising: removing said sealing material from said carrier tapeby using a heated roll to warm said sealing material for removal.
- 15. A method of chemical compound storage, as defined in Claim 2, further comprising:
- (a) perforating said carrier tape with holes between said chemical receiving wells, said holes being disposed near upper edges of said chemical receiving wells; and
- (b) evacuating space between said seal material and said carrier tape at time of sealing through said holes to assure an intimate leak tight seal is achieved between said seal material and said carrier tape.

- 16. A method of chemical compound storage, as defined in Claim 2, further comprising: die cutting said sealing material around one of said two or more matrices of said chemical receiving wells to allow manual removal of said sealing material from said pattern of said chemical receiving wells.
- 17. A method of chemical compound storage, as defined in Claim 3, further comprising: spinning said roll to force contents of said chemical receiving wells to bottoms of said chemical receiving wells by centrifugal force.
- 18. A method of chemical compound storage, as defined in Claim 1, further comprising: severing individual said two or more matrices of said chemical receiving wells from said carrier tape so that said individual said two or more matrices can be used independently.
- 21. A device for chemical compound storage, comprising: a longitudinally extending carrier tape having therein a plurality of thermoformed chemical receiving wells, said chemical wells being disposed in two or more matrices on said carrier tape.
- 22. A device for chemical compound storage, as defined in Claim 21, further comprising: a liquid tight sealing material disposed around each of said thermoformed chemical receiving wells to retain said chemical compounds therein and to minimize evaporation.
- 23. A device for chemical compound storage, as defined in Claim 22, wherein: said carrier tape is formable into a compact roll for storage, said roll having about 100,000 aliquots and dimensions of about 16 inches in diameter by four inches wide.

30. A method of chemical compound storage, as defined in Claim 1, further comprising: indexing said two or more matrices of said thermoformed chemical receiving wells using a tractor drive.